4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-M-0502, FDA-2011-M-0503, FDA-2011-M-0563, FDA-2011-M-0564, FDA-2011-M-0600, FDA-2011-M-0601, FDA-2011-M-0630, and FDA-2011-M-0707]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT:

Nicole Wolanski,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 1650,

Silver Spring, MD 20993-0002,

301-796-6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2011, through September 30, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available From July 1, 2011, Through September 30, 2011

PMA No. Docket No.	Applicant	Trade Name	Approval Date
P100031 FDA-2011-M-0502	Roche Diagnostics Corp.	ELECSYS ANTI-HBC IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HBC	June 22, 2011
P100032 FDA-2011-M-0503	Roche Diagnostics Corp.	ELECSYS ANTI-HBC IMMUNOASSAY, ELECSYS PRECICONTROL ANTI-HBC FOR USE ON THE ELECSYS 2010 IMMUNOASSAY ANALYZER	June 27, 2011
P100001 FDA-2011-M-0563	Ortho-Clinical Diagnostics, Inc.	VITROS IMMUNODIAGNOSTICS PRODUCTS ANTI-HBE REAGENT PACK, VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE CALIBRATOR, AND VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE CONTROLS	July 20, 2011
P110001 FDA-2011-M-0564	Abbott Vascular	RX HERCULINK ELITE RENAL STENT SYSTEM	July 20, 2011
P100044 FDA-2011-M-0600	Intersect ENT	PROPEL	August 11, 2011
P110020 FDA-2011-M-0601	Roche Molecular Systems, Inc.	COBAS 4800 BRAF V600 MUTATION TEST	August 17, 2011
P110012 FDA-2011-M-0630	Abbott Molecular, Inc.	VYSIS ALK BREAK APART FISH PROBE KIT; VYSIS PARAFFIN PRETREATMENT IV & POST HYBRIDIZATION WASH BUFFER KIT; PROBECHEK ALK NEGATIVE CONTROL SLIDES; AND PROBECHEK ALK POSITIVE CONTROL SLIDES	August 26, 2011
H100006 FDA-2011-M-0707	Synapse Biomedical, Inc.	NEURX DPS DIAPHRAGM PACING SYSTEM	September 28, 2011

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: January 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-537 Filed 01/12/2012 at 8:45 am; Publication Date: 01/13/2012]